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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,333	11/15/2001	Avi J. Ashkenazi	P2730P1C27	1275

35489 7590 09/13/2004

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CO 94025-3506

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,333

Applicant(s)

ASHKENAZI ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-126, 129-131 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119-123 is/are rejected.
- 7) ☒ Claim(s) 124-126, 129-131 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/6/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

- A. The Amendment dated 8/6/04 has been entered into the record.
- B. Claims 119-131 were pending in this application. In the Amendment dated 8/6/04, Applicants canceled claims 127 and 128. Therefore, claims 119-126 and 129-131 are pending and are the subject of this Office Action.
- C. The Information Disclosure Statement dated 8/6/04 has been entered into the record. All references have been considered.
- D. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Priority

- A. After review of Applicants' arguments as well as the specification, the Examiner agrees that the chondrocyte proliferation assay is specific, substantial and well-established utility. Therefore, the present invention possesses utility under 35 USC 101 and is enabled under 35 USC 112, first paragraph. Therefore, the present invention receives priority to PCT/US00/08439, filed March 30, 2000.

3. Specification

- A. Though no objection was made to the specification regarding hyperlinks, it is noted that Applicants have amended the specification to remove any hyperlinks.
- B. The objection to the specification regarding the title has been withdrawn in view of Applicants' amendment to the title to more closely reflect the claimed subject matter (i.e. PRO844 polypeptides).
- C. The specification remains objected for the reason already of record on page 3 of the Office Action mailed 5/6/04. Applicants did not address the issue regarding priority. The status of U.S. Application 09/380,137 should be updated in the first line of the specification.

Art Unit: 1647

4. Claim Objections

A. The objection to claims 119-126, 129-131 has been withdrawn in view of Applicants' amendments to the claims to replace the phrase "shown in Figure 240 (SEQ ID NO:345)" with "of SEQ ID NO:345."

B. Claims 120-123 are objected to since they depend from canceled claim 39.

C. Claim 124 is objected to since the "(d)" has not been deleted. Claims 125, 126 and 129-131 are also objected to since they depend from claim 124.

5. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. The rejection of claims 119-126 and 129-131 under 35 USC 112, first paragraph, has been withdrawn in view of the fact that Applicants have met all of the conditions for the deposit of biological materials.

B. Claims 119-123 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action mailed 5/6/04. Claims 124-126 and 129 were inadvertently included in this rejection. However, these claims recite that the polypeptide must comprise the full-length receptor and, therefore, do not raise issues of enablement under 35 USC 112, first paragraph.

Applicants have removed reference to the "extracellular domain." Therefore, this part of the rejection is obviated. Regarding claims 119-123, Applicants argue that the claims have been amended to include a functional recitation "wherein, said polypeptide induces chondrocyte proliferation" and that this assay is well-described in at least Example 160. Based on this, the artisan would not require undue experimentation to make and use the claimed invention.

These arguments have been considered, but are not deemed persuasive. The Examiner does not question that the chondrocyte proliferation assay is well-described in the specification. The Office Action mailed 5/6/04 states that "the claims are broad because they do not require the claimed polypeptide to be identical to the disclosed sequence and because the claims have no functional limitation." While Applicants have amended the claims to recite a functional limitation, the issue remains that the claims are broad because they do not require the claimed polypeptide to be identical to the disclosed sequence (SEQ ID NO:345). Applicants have only enabled the use of the full-length protein of SEQ ID NO:345 (and that

Art Unit: 1647

encoded by ATCC No. 209976) to induce chondrocyte proliferation. The only disclosure regarding PRO844 (SEQ ID NO:345) can be found on pages 215 and 362 of the specification. Nowhere in the specification do Applicants disclose working examples of polypeptides which are less than the full-length of SEQ ID NO:345. Polypeptides which are less than the full-length of SEQ ID NO:345 would have one or more amino acid substitutions, deletions, insertions and/or additions to the polypeptide of SEQ ID NO:345. Applicants have not provided any guidance as to what critical residues are required to maintain the functional characteristics (i.e. chondrocyte proliferation) of the polypeptide of SEQ ID NO:345, nor is it predictable to one of ordinary skill in the art how to make a functional polypeptide which is less than 100% identical to that of SEQ ID NO:345.

In summary, the breadth of the claims remains excessive with regard to Applicants claiming all polypeptides which are less than the full-length of SEQ ID NO:345. There is also a lack of guidance and working examples of these polypeptides as well as which residues are critical for polypeptide function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a functional polypeptide other than that of SEQ ID NO:345 leads the Examiner to maintain that undue experimentation is necessary to practice the invention as claimed. It is believed that all pertinent arguments have been addressed.

6. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 119-123 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to include a functional limitation. Claims 124-126 and 129 were inadvertently included in this rejection. However, these claims recite that the polypeptide must comprise the full-length receptor and, therefore, do not raise issues of written description under 35 USC 112, first paragraph. Regardless, the issue is moot in view of Applicants' amendments to the claims.

7. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 119-131 under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' amendment to the claims to remove recitation of "extracellular domain."

8. Conclusion

A. Claims 124-126 and 129-131 would be allowable if they were amended to overcome the objection as recited in paragraph C under "Claim Objections."

Art Unit: 1647

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
September 09, 2004


ROBERT LANDSMAN
PATENT EXAMINER